ANTIBODY SYSTEMS, INC.
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September 15, 2004

Steven A. Masiello
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1488
Phone: 301.827.6347

Re: April 14, 2003
Warning Letter
CBER-03-010

Dear Mr. Masiello:

This follows an August 26, 2004 letter from Joanne Binkley and represents a formal request that you post this letter on the Food and Drug Administration ("FDA") website as a response to the above-referenced Warning Letter.

This letter should not have been directed to either our firm or me personally. The FDA inspection on December 16-17, 2002 which resulted in the issuance of this letter took place at the office of the North Texas Institutional Review Board ("NTIRB") and both the FORM FDA 482 (12/16/02) and FORM FDA 483 (12/17/02) were issued to Neil H. Dishon, M.D./former IRB Chairman. Moreover, Dr. Dishon responded in writing on 01/22/03 to each observation on the FORM 483.

We received from Dr. Dishon and have carefully reviewed a copy of the Establishment Inspection Report ("EIR"). As this EIR document clearly reflects on page 3 of 29 pages under the heading "PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITIES", Dr. Dishon

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"is the most responsible person and has knowledge of all the previous activities of the board." Additionally, "All correspondence should be directed to him...". No representative of Antibody Systems, Inc. ("ASI") was issued a FORM FDA 482 or subject to any inspection by the FDA. Consequently, it was inappropriate and contrary to FDA policy to direct the letter to me.

ASI undertook to respond to this letter on May 7, 2003 as a courtesy to Dr. Dishon. We were not aware of FDA's policy to make these letters public and place them on the FDA website. Had we known at the time, we would have provided a different communication. We questioned the basis for some of the comments in the FDA letter but did not contest them. However, our subsequent review of the EIR causes us to question the accuracy of the content and the very allegations in the FDA letter.

Consequently, in addition to our request to post this letter on the FDA website immediately, I also request that you withdraw the original and direct it to NTIRB as required by your own policy and procedure.

Sincerely,

Terry M. Fredeking
President
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cc: Ms. Patricia Holobaugh
Michael A. Chappell
Dr. Kristina Borror
Joanne Binkley